PART 12—SPECIAL CLASSES OF MERCHANDISE

1. The general and relevant specific authority citations for part 12 continue to read as follows:

Authority: 5 U.S.C. 301, 19 U.S.C. 66, 1202 (General Note 20, Harmonized Tariff Schedule of the United States (HTSUS)), 1624;

* * * * *

Section 12.39 also issued under 19 U.S.C. 1337, 1623;

* * * * *

2. Section 12.39 is amended by revising the heading of paragraph (b); by adding a new paragraph (b)(4); by redesignating paragraphs (c) and (d) as paragraphs (d) and (e); and by adding a new paragraph (c) to read as follows:

§ 12.39 Imported articles involving unfair methods of competition or practices.

* * * * *

(b) *Exclusion from entry; entry under bond; notice of exclusion order.* * * *

(4) In addition to the notice given to importers or consignees of articles released under bond, port directors shall provide written notice to all owners, importers or consignees of articles which are denied entry into the United States pursuant to an exclusion order that any future attempt to import such articles may result in the articles being seized and forfeited. Copies of all such notices are to be forwarded to the Commercial Enforcement, Trade Compliance Division, at Customs Headquarters, and to the Office of The General Counsel, USITC, 500 E Street, SW., Washington, DC 20436 by the district directors.

(c) *Seizure and Forfeiture Orders.* (1) In addition to issuing an exclusion order under paragraph (b)(1) of this section, the Commission may issue an order providing that any article determined to be in violation of § 337 be seized and forfeited to the United States. Such order may be issued if:

(i) The owner, importer, or consignee of the article previously attempted to import the article or like articles into the United States;

(ii) The article or like articles were previously denied entry into the United States by reason of an exclusion order issued under paragraph (b)(1) of this section; and

(iii) Upon such previous denial of entry, the port director of the port in which the entry was attempted had notified the owner, importer, or consignee of the article in writing of both the exclusion order and that seizure and forfeiture would result from any further attempt to import the article or like articles into the United States.

(2) Upon receipt of any seizure order issued by the Commission in accordance with this paragraph, Customs shall immediately notify all ports of entry of the property subject to the seizure order and identify the persons notified under paragraph (b)(4) of this section.

(3) The port director in the port in which the article was seized shall issue a notice of seizure to parties known to have an interest in the seized property. All interested parties to the property shall have an opportunity to petition for relief under the provisions of 19 CFR part 171. All petitions must be filed within 30 days of the date of issuance of the notice of seizure, and failure of a claimant to petition will result in the commencement of administrative forfeiture proceedings. All petitions will be decided by the appropriate Customs officer, based upon the value of the articles under seizure.

(4) If seized articles are found to be not includable in an order for seizure and forfeiture, then the seizure and the forfeiture shall be remitted in accordance with standard Customs procedures.

(5) Forfeited merchandise shall be disposed of in accordance with the Customs laws.

* * * * *

George J. Weise,

Commissioner of Customs.

Approved: October 10, 1995.

John P. Simpson,

Deputy Assistant Secretary of the Treasury.

[FR Doc. 95–26718 Filed 10–26–95; 8:45 am]

BILLING CODE 4820–02–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 522

Implantation or Injectable New Animal Drugs; Flunixin Meglumine Solution

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending the animal drug regulations to reflect approval of an abbreviated new animal drug application (ANADA) filed by Phoenix Scientific, Inc. The ANADA provides for intravenous or intramuscular use of flunixin meglumine injection for alleviation of inflammation and pain associated with musculoskeletal disorders and visceral pain associated with colic in horses.

EFFECTIVE DATE: October 27, 1995.

FOR FURTHER INFORMATION CONTACT: Sandra K. Woods, Center for Veterinary Medicine (HFV–114), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301–594–1616.

SUPPLEMENTARY INFORMATION: Phoenix Scientific, Inc., 3915 South 48th Street Ter., P.O. Box 6457, St. Joseph, MO 64506–0457, filed ANADA 200–124, which provides for intravenous or intramuscular use of flunixin meglumine injection for alleviation of inflammation and pain associated with musculoskeletal disorders and visceral pain associated with colic in horses.

Approval of ANADA 200–124 for Phoenix Scientific's flunixin meglumine injection is as a generic copy of Banamine® (flunixin meglumine) Injection in Schering-Plough Animal Health's NADA 101–479. The ANADA is approved as of September 25, 1995, and the regulations are amended in § 522.970(b) (21 CFR 522.970(b)) to reflect the approval. The basis for approval is discussed in the freedom of information summary.

In accordance with the freedom of information provisions of part 20 (21 CFR part 20) and § 514.11(e)(2)(ii) (21 CFR 514.11(e)(2)(ii)), a summary of safety and effectiveness data and information submitted to support approval of this application may be seen in the Dockets Management Branch (HFA–305), Food and Drug Administration, rm. 1–23, 12420 Parklawn Dr., Rockville, MD 20857, between 9 a.m. and 4 p.m., Monday through Friday.

The agency has determined under 21 CFR 25.24(d)(1)(i) that this action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

List of Subjects in 21 CFR Part 522

Animal drugs.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs and redelegated to the Center for Veterinary Medicine, 21 CFR part 522 is amended as follows:

PART 522—IMPLANTATION OR INJECTABLE DOSAGE FORM NEW ANIMAL DRUGS

1. The authority citation for 21 CFR part 522 continues to read as follows:

Authority: Sec. 512 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360b).

2. Section 522.970 is amended by revising paragraph (b) to read as follows:

§ 522.970 Flunixin meglumine solution.

* * * * *

(b) *Sponsors.* See Nos. 000061, 000856, and 059130 in § 510.600(c) of this chapter.

* * * * *

Dated: October 17, 1995.

Stephen F. Sundlof,

Director, Center for Veterinary Medicine.

[FR Doc. 95–26633 Filed 10–26–95; 8:45 am]

BILLING CODE 4160–01–F

21 CFR Part 886

[Docket No. 91N–0063]

Immunology and Microbiology Devices; Revocation of the Exemption From Premarket Notification; Blood Culturing System Devices; Change of Compliance Date

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule; change of compliance date for certain manufacturers and distributors.

SUMMARY: The Food and Drug Administration (FDA) is changing the compliance date of the final rule published on July 27, 1995 (60 FR 38480), that revoked the exemption from the requirement of premarket notification for blood culturing system devices to allow a 60-day grace period for submission of premarket notifications and to change the April 22, 1996, deadline to a December 26, 1996, deadline for obtaining premarket clearance for manufacturers or initial distributors of the device that have already begun commercial distribution under the existing premarket notification exemption. This action is being taken in response to a request to reconsider the procedural requirements of the final rule.

DATES:

Effective date: The final rule is effective October 25, 1995.

Compliance dates: A premarket notification submission is required for any automated blood culturing system intended to be introduced or delivered for introduction into commerce on or after October 25, 1995, under section 510(k) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360(k)), and the procedures in subpart E of 21 CFR part 807. A manufacturer or an initial distributor of a blood culturing device that has already begun commercial distribution under the existing premarket notification exemption is required to submit a premarket notification on or before December 26, 1995, and must have a premarket notification cleared by FDA by December 26, 1996.

FOR FURTHER INFORMATION CONTACT: Lisa A. Rooney, Center for Devices and Radiological Health (HFZ–84), Food and Drug Administration, 2094 Gaither Rd., Rockville, MD 20850, 301–594–4765, ext. 164.

SUPPLEMENTARY INFORMATION: In the Federal Register of November 9, 1982 (47 FR 50814 at 50826), FDA published a final rule to classify blood culturing system devices into class I (21 CFR 866.2560). In the Federal Register of June 12, 1989 (54 FR 25042 at 25046), FDA published a final rule exempting microbial growth monitors, subject to certain limitations. In the Federal Register of April 26, 1991 (56 FR 19333), FDA proposed to revoke this exemption for blood culturing system devices because of safety and effectiveness considerations. In the proposed rule, FDA stated that a manufacturer or an initial distributor who has introduced blood culturing system devices into commerce since the premarket notification exemption became effective would be required to submit to FDA a premarket notification within 60 days after the final rule based upon the proposal became effective.

In the Federal Register of July 27, 1995 (60 FR 38480), FDA published a final rule to revise the microbial growth monitor classification regulation by revoking the exemption from the premarket notification requirements for automated blood culturing system devices used in testing blood and other normally sterile body fluids for bacteria, fungi, and other microorganisms. According to the final rule, a manufacturer or an initial distributor of a blood culturing device that had already begun commercial distribution under the existing premarket notification exemption would be required to submit a premarket notification on or before October 25, 1995, and have a premarket notification cleared by FDA by April 22, 1996.

In response to a letter requesting FDA to reconsider the procedural requirements of the final rule of July 27, 1995, FDA has decided to allow a 60-day grace period for submission of premarket notifications for manufacturers or initial distributors who have already begun introducing blood culturing system devices into commerce under the existing premarket notification exemption. However, a premarket notification submission is still required for any automated blood culturing system intended to be introduced or delivered for introduction into interstate commerce on or after October 25, 1995. Furthermore, in response to the correspondence, FDA has decided to change the April 22, 1996, deadline to a December 26, 1996, deadline for obtaining premarket clearance.

Dated: October 23, 1995,

William B. Schultz,

Deputy Commissioner for Policy.

[FR Doc. 95–26678 Filed 10–26–95; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF THE TREASURY

Internal Revenue Service

26 CFR Part 1

[TD 8626]

RIN 1545–AT15

Continuity of Interest in Transfer of Target Assets After Qualified Stock Purchase of Target

AGENCY: Internal Revenue Service (IRS), Treasury.

ACTION: Final regulations.

SUMMARY: This document prescribes final regulations under section 338 of the Internal Revenue Code regarding the transfer of target assets to the purchasing corporation or another member of the same affiliated group as the purchasing corporation after a qualified stock purchase (QSP) of target stock, if a section 338 election is not made. These regulations provide guidance to parties to such transfers.

DATES: These regulations are effective October 27, 1995.

These regulations are applicable to transfers of target assets that occur on or after October 26, 1995.

FOR FURTHER INFORMATION CONTACT: Steven M. Flanagan at (202) 622–7790 (not a toll-free number).

SUPPLEMENTARY INFORMATION:

Explanation of Provisions

Background

This document contains final regulations under section 338 that govern the treatment of an intragroup merger or similar transaction following a QSP of target stock, if a section 338 election is not made for the target.

Section 338 provides that, if a corporation makes a QSP of the stock of a target, the purchasing corporation may elect to have the target treated as having sold all of its assets at the close of the acquisition date in a single transaction and as a new corporation that purchased all such assets at the beginning of the following day. Under section 338(i), the